

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/082,492 Confirmation No.: 4234
Applicant : Gene Samson et al.
Filed : February 22, 2002
TC/A.U. : 3733
Examiner : Araj, Michael J.
Title: MECHANICAL CLOT TREATMENT DEVICE WITH DISTAL FILTER
Docket No. : 1001.1763103
Customer No. : 28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENT

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Commissioner for Patents
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By _____

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JoAnn Lindman

Dear Sir:

Appellants have carefully reviewed the Final Office Action dated June 5, 2006 and the Advisory Action dated August 24, 2006. Currently, claims 21-35 are pending in the application, and all pending claims have been rejected. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 21, 22 and 24-31 were rejected under 35 U.S.C. §103(a) as being anticipated by Engelson et al., U.S. Patent No. 5,972,019 (hereinafter "Engelson"). Appellants traverse this rejection. In order for a reference to render a claim obvious, each and every element of the claim must be present in the reference. See M.P.E.P. §2143.03. Independent claims 21 and 26 recite, in part, a cage assembly including a proximal cage and a distal cage. Although the Examiner has stated that Engelson "does not disclose a cage assembly including a proximal cage and a distal

cage,” the Examiner continues to assert that “it would have been obvious” to construct the device of Engelson “having a proximal and distal cage, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.” See pages 3-4 of the June 5, 2006 Office Action, where the Examiner cites *St. Regis Paper Co. v Bemis Co.*, 549 F2d 833 (7th Cir. 1977) in support of this proposition. Appellants assert that this is an incorrect application of *St. Regis Paper*, and claims 21, 22 and 24-31 are not obvious in view of Engelson.

In *St. Regis Paper*, the Seventh Circuit Court of Appeals held that a patent was invalid for obviousness. An issue was whether adding additional plies to a bag was obvious. The court stated that “section 103 cannot easily be satisfied by inventions that rearrange old elements in new combinations with each element performing the same function it performed in the prior art, even though the new combination produces a more striking result than the old ones.” 549 F2d 833, 838 (emphasis added). The court held that, in the case of adding more layers to a bag, the additional layers simply perform the same function as the original layers, and held that such a modification would be obvious under 35 U.S.C. §103. However, the court indicated that, where the duplication of features results in “an effect greater than the sum of the several effects taken separately,” the combination would not be obvious; simply put, if the duplication of the elements results in a structure that has different capabilities, the *St. Regis Paper* court apparently indicated that the claimed subject matter would not be obvious. See *id.*, 549 F2d 833, 838, *citing Black Rock v Pavement Co.*, 396 U.S. 57, 61 (1969).

In contrast to the additional layers of a bag that do not add different capabilities in *St. Regis Paper* case, the multiple cage design of claims 21 and 26 does add different capabilities compared to a single cage design. The devices of claims 21 and 26 have both a proximal and a distal cage. As described in the specification, these multiple cages can provide different capabilities compared to a single cage design. In one example, the proximal cage can break up a clot or other arterial blockage while the other cage can be a distal filter member that is “placed distal to the thrombus to catch any portions which may break away.” See paragraph [0003] of the application. Simply put, each cage of claims 21 and 26 does not perform “the same function it performed in the prior art,” as stated in *St. Regis Paper*. Because the multiple cage design results in additional capabilities over a single cage design and each cage does not perform “the same function it performed in the prior art,” claims 21, 22 and 24-31 cannot be obvious under the doctrine of *St. Regis Paper*.

In addition to incorrectly applying the *St. Regis Paper* case to support the obviousness rejection of claims 21, 22 and 24-31, the Examiner further appears to suggest in error that Applicants must establish that the proximal and distal cage limitations are “critical” in order to overcome the Examiner’s arguments. On page 6 of the June 5, 2006 Office Action, for example, the Examiner states:

Applicant’s arguments filed March 2, 2006 have been fully considered but they are not persuasive. Applicant’s arguments with regard to claims 21-31 do not overcome the rejections applied thereto, since applicant has not provided any convincing showing that these are nothing more than duplication of parts as asserted by the examiner. Applicant has not provided any showing that such limitations are “critical”. In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973).

Applicants have carefully reviewed the *In re Cole*, *In re Kuhle*, and *In re Davies* decisions cited by the Examiner (see above), and assert that these cases do not require a showing that the limitations regarding the proximal and distal cages be “critical”, as asserted by the Examiner. The only decision which appears directed to whether recited limitations are “critical” is the *In re Cole* decision, which discusses the criticality of claim limitations involving proportions or concentrations in composition of matter or process claims. Nothing in any of these cases discusses “critical” claim limitations where duplicative features are alleged to be obvious. Accordingly, Applicants assert that the Examiner’s statement that there must be a showing that such claim limitations are “critical” is incorrect.

For at least the above reasons, claims 21 and 26 are allowable over Engelson. In addition, because they are dependent on claims 21 and 26 and because these claims recite additional patentably distinct elements, claims 22 and 24, 25 and 27-31 are also allowable over this reference.

Claims 21-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmaltz et al., U.S. Patent No. 5,449,372 (hereinafter “Schmaltz”) in view of Crittenden et al., U.S. Patent No. 4,719,924. Again, while acknowledging that neither reference discloses a cage assembly including both a proximal and distal cage, the Examiner nevertheless asserts that it would have been obvious to provide a proximal and distal cage “since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.” See the June 5, 2006 Office Action at p. 6 (citing *St. Regis Paper*). Further, the Examiner also stated that the Appellants have not shown that any of the features are “critical.” See the June 5, 2006

Office Action at p. 6 (citing *In re Cole*, *In re Kuhle*, and *In re Davies*). As mentioned above, the Examiner's application of *St. Regis Paper*, *In re Cole*, *In re Kuhle*, and *In re Davies* is incorrect. The use of multiple cages in claims 21 and 26 versus the single stent portion 14 in Schmaltz is not obvious under the holding in *St. Regis Paper* and nothing in *In re Cole*, *In re Kuhle*, and *In re Davies* mentions the need for a showing of the criticality of an element in a situation such as the current application. As such, claims 21-31 are not obvious in view of these references.

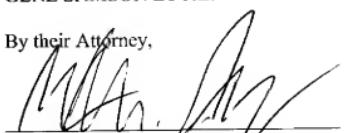
Claims 32-35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engelson in view of Lefebvre, U.S. Patent No. 5,421,832. As mentioned above, Engelson does not disclose each and every element of claim 26. In addition, Lefebvre does not disclose the elements of claim 26 that are missing from Engelson. Because they are dependent on claim 26 and because they recite additional patentably distinct elements, claims 32-35 are allowable over these references.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
GENE SAMSON ET AL.

Date: Nov. 2, 2006

By their Attorney,


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